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April 28, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville MD 20852

RE: Docket Number 99D-0557

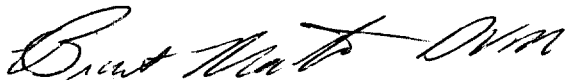
I have reviewed the document "Guidance for Industry; Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans" as a practicing veterinarian specialized in laboratory animal and primate medicine.

I agree that the health risks posed by xenotransplantation are substantial. I also agree that currently insufficient information exists to protect the public health from these risks.

I recommend that the document be modified to further expound on the fact that there are currently known adventitious organisms of nonhuman primates for which tests are not available and that the body of knowledge of potential infectious organisms of nonhuman primates is wholly inadequate. These are substantial barriers to reasonably safe xenotransplantation.

Additional guidelines are needed to address xenotransplantation using tissues from other species. The health risks from even a well characterized species such as swine appear substantial.

Sincerely,

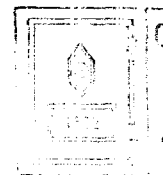


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